Participant Consent Form for PwMs

Study title: Scaling EUROpean citizen driven transferable and transformative digital health (SEURO): An Effectiveness-Implementation Hybrid Trial

I have read and understood the Participant Information Leaflet about this study. The information has also been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes**	**No**
I understand that I do not have to take part in this study and that I can opt out at any time. I understand that I do not have to give a reason for opting out and that opting out will not affect my current or future access to healthcare treatments or services.	**Yes**	**No**
I give my permission for information collected about me to be stored and electronically processed for the purposes of this research study, and for it to be used in other studies in the future but only if approved by a Research Ethics Committee.	**Yes**	**No**
I understand that the information collected about me will remain private and confidential. I understand that this information will be stored securely in a pseudonymised record, and the published findings will not be linked to my name in any way.	**Yes**	**No**
I give my permission for pseudonymised information collected about me (e.g., my data from the ProACT technology) to be shared with other partners in the SEURO project, including imec in Belgium, Umea University in Sweden and IBM Ireland, for purposes of analysis.	**Yes**	**No**
I understand that if I disclose to a member of the research team information about unacceptable work practices in a healthcare setting or by a healthcare professional that have affected me, the researcher is obliged to report this to the relevant management. I give consent for this and understand that my identity may be revealed in this instance.	**Yes**	**No**

I understand that if I am randomly assigned to the relevant groups (i.e., the groups that will receive and use the technology), the technology in question is designed to help me to understand and manage my health conditions but does not affect or replace my ongoing healthcare treatments or services.	**Yes**	**No**
I understand that if I am randomly assigned to the relevant groups (i.e., the groups that will receive and use the technology), the technology in question will be removed from my home at the end of my study participation period (i.e., after six months).	**Yes**	**No**
I understand that if I am randomly assigned to the relevant groups (i.e., the groups that will receive and use the technology), and that if I do not have a broadband internet connection in my home, a mobile internet connection will be provided free of charge during my study participation period. I understand that after this time, the mobile internet connection will be discontinued.	**Yes**	**No**
I understand that if I am randomly assigned to group 3 that I will not receive any of the technology described in the Participant Information Leaflet.	**Yes**	**No**
If randomly assigned to the relevant group (i.e., the group that receives the support of a clinical triage service), I consent to my vital signs' information, collected via the technology, being monitored by the clinical triage service, using their own version of the technology. I understand that this service is only available to monitor my vital signs during normal working hours (i.e., between 9am and 5pm Monday to Friday). I also understand that this service will no longer be available to me after my study participation period concludes.	**Yes**	**No**
I understand that if I am worried about my health or feeling unwell at any time during the study, I should follow my usual healthcare plan (e.g., by contacting my GP or emergency service).	**Yes**	**No**

I understand that my doctors will not use information collected about me during this study to inform their clinical decision-making regarding my healthcare.	**Yes**	**No**
If randomly assigned to group one or group two, I give my permission for the interviews to be audio recorded. I understand that these recordings are only made so that they can be analysed in-depth at a later time. I also understand that these recordings will be deleted once the analysis is complete.	**Yes**	**No**
If randomly assigned to the relevant groups (i.e., the groups that will receive and use the technology, and will subsequently participate in interviews about their experiences), I give my permission for photographs of me using the technology to be taken during the interviews. I understand that these may be used in reports and publications and that I can refuse consent for any photograph to be used at any time up until it is published. I understand that I will be shown any photographs before they are published to ensure that I am satisfied with them. Please Note: You do not have to consent for photographs to be taken in order to participate in the interviews or the overall study.	**Yes**	**No**
I have received a copy of the Participant Information Leaflet and this completed consent form for my records.	**Yes**	**No**

Participant Name (Block Capitals)	Participant Signature	Date

To be completed by the Researcher:

I, the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals)	Qualifications	Signature	Date